UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSE, TEXAS, VIRGINIA, WASHINGTON, and WISCONSIN; the DISTRICT OF COLUMBIA, the CITY OF CHICAGO, and the CITY OF NEW YORK; *ex rel.*, CHARLES ARNSTEIN AND HOSSAM SENOUSY,

Plaintiffs and Relators,

-against-

13 Civ. 3702 (CM)

TEVA PHARMACEUTICALS USA, INC., TEVA NEUROSCIENCE, INC., and TEVA SALES AND MARKETING, INC.

Defendants.

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ORDER DISPOSING OF MOTIONS *IN LIMINE*

McMahon, C.J.:

The Court, for its rulings on the motions *in limine*:

DEFENDANTS' MOTIONS IN LIMINE

I. Defendants' Motions *in Limine* to Exclude Testimony of Relators' Experts

Defendants Teva Pharmaceuticals USA, Inc., Teva Neuroscience, Inc., and Teva Sales and Marketing, Inc. ("Defendants" or "Teva") move to exclude the expert opinion testimony of Plaintiff-Relators' experts: (1) Dr. Joel W. Hay; (2) Dr. Holly J. Humphrey; (3) Dr. Samuel

Pleasure; and (4) Paul W. Kim, pursuant to Fed. R. Evid. 401, 403, and 702. Teva did not file *Daubert* motions seeking to exclude these experts' testimony in connection with its motion for summary judgment; it does so now through four motions *in limine*.

For the reasons that follow, Teva's motions are denied in substantial part.

A. Applicable Standard

Federal Rule of Evidence 702 codifies the standard for admissibility set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), under which the Court's role is to determine whether the expert is qualified to testify. *Id.* at 589; Fed. R. Evid. 702. *See generally In re Namenda Direct Purchaser Antitrust Litig.* ("*Namenda*"), 331 F. Supp. 3d 152, 168 (S.D.N.Y. 2018). As this Court noted, "The standard to evaluate non-scientific expert testimony is whether the expert bases testimony upon professional studies or personal experience and employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Namenda*, 331 F. Supp. 3d at 168 (internal quotation omitted).

B. Dr. Joel W. Hay

1. Dr. Hay's Qualifications

Dr. Hay, a pharmaceutical economist, is a tenured Full Professor and Founding Chair of Pharmaceutical Economics and Policy in the School of Pharmacy at the University of Southern California, with joint appointments in the Schaeffer Center for Health Policy and Economics and in the Department of Economics. (Expert Report of Dr. Joel W. Hay, Ph.D. ("Hay Report") ¶ 5, Ex. 1 to Decl. of Timothy J. Geverd in Supp. of Defs.' Mot. *in Limine* to Exclude Op. Test. of Dr. Joel W. Hay ("First Geverd Decl."), Dkt. No. 187-2; *see also id.* App'x A.) Dr. Hay has extensive experience consulting and advising various research bodies, governmental agencies, and policy organizations, and has authored over 200 peer-reviewed scientific articles and commentaries in the fields of pharmaceutical economics and health economics, among others. (*Id.* ¶¶ 6–10); *see also*

United States ex rel. Garbe v. Kmart Corp., No. 12-cv-881, 2017 WL 3175983, at *2 (S.D. Ill. July 21, 2017) (finding that Dr. Hay's "expertise and experience in economics, specifically pharmaceutical economics, renders him more than competent" to "opine on the damages allegedly sustained by the Government").

Teva does not challenge Dr. Hay's extensive qualifications. Rather, Teva challenges Dr. Hay's methodology as unsound.

2. Overview of Dr. Hay's Report

As the Court noted in denying Teva's motion for summary judgment, Dr. Hay, Relators' damages expert, "identified two potential sets of false claims submitted within the Relevant Period" of 2006 to 2015.[1] *United States ex rel. Arnstein v. Teva Pharm. USA, Inc.*, No. 13-cv-3702, 2019 WL 1245656, at *24 (S.D.N.Y. Feb. 27, 2019) (hereinafter, "*Teva*"). The first is predicated on claims submitted to four federal health care programs—Medicare Part D, Medicaid, TRICARE, and the Veterans Administration ("VA")—"at any time after [a] speaker was paid by Teva to speak about Azilect or Copaxone, through the end of the Relevant Period," *i.e.*, 2015. (*Id.*) The second is predicated on claims that were submitted to those same federal health care programs "within six months of a speaker's being paid to speak about a given drug [] at a 'sham' speaker program, the criteria for which were identified by Relators' [other] expert Dr. Humphrey." (*Id.* at *25.) Dr. Hay calculated two alternative damages figures for each model based on (*i*) actual claims data and, (*ii*) for time periods where the data was incomplete, a time series regression analysis. (Hay Report ¶¶ 45–58.) Dr. Hay was unable to obtain data from the VA about Azilect and

[1] The parties' Second Amended and Updated Proposed Joint Pre-Trial Order lists the Relevant Period as 2006 to 2014, not 2015. (Dkt. No. 203 at 10.)

Copaxone prescriptions, and so used the overall ratio of VA prescription spend to Medicare Part D prescription spend to calculate Azilect and Copaxone claims. (*Id.* ¶¶ 52–55.)

3. Regression Analysis

Teva first challenges the subset of Dr. Hay's damages calculations based not on actual claims data, but on projections. (Defs.' Mot. *in Limine* to Exclude Expert Op. Test. of Dr. Joel W. Hay, Dkt. No. 187 at 2–3.) Because there were gaps in the claims information (*i*) for Medicare Part D for the years 2006 to 2009; and (*ii*) for Tricare from March 23, 2010 through December 31, 2010 and for all 2015, Dr. Hay conducted a time series regression analysis to project that missing information (number of claims and total cost), and calculated damages based on those projections. (Hay Report ¶¶ 45, 48, 52.) Teva challenges the regression analysis on the ground that Dr. Hay used only one explanatory variable—time expressed by year—and did not include any confounding variables in his analysis. (Dkt. No. 187 at 2.) According to Teva, this makes Dr. Hay's testimony "so incomplete as to be irrelevant." (*Id.* (quoting *Bickerstaff v. Vassar Coll.*, 196 F.3d 435, 449 (2d Cir. 1999), *as amended on denial of reh'g* (Dec. 22, 1999)).)

"Normally, failure to include variables will affect the analysis' probativeness, not its admissibility." *Bazemore v Friday*, 478 U.S. 385, 400 (1986); *see also Chen-Oster v. Goldman, Sachs & Co.*, 325 F.R.D. 55, 71 (S.D.N.Y. 2018). However, "some regressions [may be] so incomplete as to be inadmissible as irrelevant." *Bazemore*, 478 U.S. at 400 n.10. Among other ways, this occurs "[w]here significant variables that are quantifiable are omitted from a regression analysis." *Freeland v. AT&T Corp.*, 238 F.R.D. 130, 145 (S.D.N.Y. 2006). "Because the burden of proving helpfulness and relevance rests on the proponent of a regression analysis, it is the proponent who must establish that the major factors have been accounted for in a regression analysis." *Id.* At the same time, a defendant challenging a regression analysis must at least identify the significant, missing variables. *Sobel v. Yeshiva Univ.*, 839 F.2d 18, 34 (2d Cir. 1988). While

the burden to show relevance and admissibility always rests with the proponent, "a mere conjecture or assertion on the defendant's part" is insufficient. *Id.* (internal quotation omitted).

Teva fails to meet this minimal burden. Rather, Teva makes the conclusory argument that the failure to include any variables besides time *ipso facto* renders Dr. Hay's analysis incomplete. (Dkt. No. 187 at 3.) In all the cases Teva cites, the party challenging the regression had either identified the "significant" missing variables, or it was patently obvious in light of the record what those missing variables were. *See, e.g.*, *Bickerstaff*, 196 F.3d at 449–50 (regression showing connection between race and salary among college faculty was not admissible, since expert failed to control for faculty members' scholarship, teaching evaluations, and duration of service); *Bazemore*, 478 U.S. at 402 ("petitioners presented evidence to rebut respondents' contention that county-to-county variations in contributions to salary explain the established disparity between black and white salaries"); *Freeland*, 238 F.R.D. at 146 (expert's wholesale price model was not admissible, since it did not account for the shift from analog to digital handsets, or for changes in product quality, over the relevant period); *see also In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 299 F. Supp. 3d 430, 484 (S.D.N.Y. 2018) (regression analysis inadmissible because fixed data inputs "strongly suggest[ed] cherry-picking").

The same cannot be said here. Teva's moving papers do not identify a single "significant variable" that was omitted from Dr. Hay's analysis. (*See* Dkt. No. 187 at 2–3.) The closest that Teva comes is attaching excerpts from Dr. Hay's deposition—without discussing same in their briefs—that show that he was questioned about whether the entry of competitor drugs into the marketplace was a possible "confounding" variable. (Ex. 5 to First Geverd Decl., Dkt. No. 187-6 at 205:10–22.) Conspicuously, the deposition excerpts attached to the motion fail to include Dr. Hay's responses to that question. (*See id.*) It is impossible for the Court to conclude, from a

question about a variable for which no answer was provided, that Dr. Hay's regression analysis is fatally flawed—particularly because Teva does not identify the competitor drug that would have driven down Azilect or Copaxone prescriptions for patients on federal health care programs, thereby altering the time series projections.

In addition, for this subset of data, Dr. Hay was asked to take actual, existing claims data and make projections to cover certain gaps in the data, or to project the data forward one year. Projecting damages this way using a log-linear regression is common. *See, e.g.*, *DPWN Holdings (USA), Inc. v. United Air Lines, Inc.*, No. 11-cv-564, 2019 WL 1515231, at *11 (E.D.N.Y. Feb. 21, 2019).

4. Veterans Administration ("VA") Damages Calculations

Teva next challenges Dr. Hay's calculations of damages for the VA, which are not based on actual claims data from the VA—none was available—but are instead calculated by (1) taking the ratio of VA total drug expenditures to Medicare Part D total drug expenditures for each year from 2006 to 2015 and (2) applying that ratio to Medicare claims and prescription costs for Copaxone and Azilect. (Dkt. No. 187 at 3 (citing Hay Report ¶ 52).) Teva takes issue with Dr. Hay's selection of Medicare Part D data as an acceptable proxy for VA data, because Dr. Hay did not conduct an "independent analysis, statistical, economic or otherwise, to make any comparison of the patient population in Medicare with the patient population in the VA." (*Id.*) Instead, Dr. Hay chose Medicare Part D as a proxy based on a single RAND study, which reported that "the median age of VA patients is over 65 and they have a higher prevalence of key health conditions than nonveterans." (*Id.* (internal quotation omitted).) Therefore, there was "unlikely to be an upward bias when applying [his] expenditure ratios to Medicare Copaxone and Azilect claims to project VA damages." (*Id* (internal quotation omitted).)

Here, the Court finds that Dr. Hay has not met his burden to demonstrate that his analysis was scientifically sound, and that Medicare Part D was the relevant patient population proxy. Independently examination of the RAND study does not appear to support Dr. Hay's conclusion. While the report states that 52.2% of veterans who are VA patients are over the age of 65, approximately 84% of Medicare beneficiaries are over the age of 65. *Compare* RAND Corp., *Assessment A (Demographics)* at xii (Sept. 1, 2015), https://www.va.gov/opa/choiceact/documents/assessments/Assessment_A_Demographics.pdf ("RAND Study") *with* Ctrs. for Medicare & Medicaid Servs., *Medicare Beneficiaries at a Glance for 2016* (Feb. 25, 2019), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Beneficiary-Snapshot/Bene_Snapshot.html; *see also* Fed. R. Civ. P. 201; *Christa McAuliffe Intermediate Sch. PTO, Inc. v. de Blasio*, 364 F. Supp. 3d 253, 262 (S.D.N.Y. 2019) (court may take judicial notice of statistics from government websites). It is not clear why these evident demographic disparities can be easily discounted, or why they make an upward bias less likely, especially as Parkinson's disease tend to strike later in life.

Further, as Teva points out, MS affects women at a rate two to three times greater than men, and the VA population is almost entirely male. (Dkt. No. 187 at 4.) Dr. Hay does not explain why this significant demographic departure would not affect his results. Instead, he explained, "the issue here isn't gender, it's how sick these people are, and VA beneficiaries tend to be pretty sick." (Ex. 9 to First Geverd Decl., Dkt. No. 187-10 at 226:10–13.)

This conclusion might have been relatively easy to support with data—at least with respect to Copaxone.[2] The RAND study does include some data on the prevalence of MS among VA patients, although it is mixed with data from encounters with the Military Health System ("MHS")

[2] The RAND study contains no data on Parkinson's disease.

overall, broken out into eight priority groups, or isolated only with respect to patients under the age of 35, respectively. *See* RAND Study at C-47, C-49, C-53. Nonetheless, it might have been possible to show that the incidence of MS in the Medicare Part D population mirrored the incidence of MS in the VA population. Dr. Hay did not do this.

In the absence of any comparison in the RAND report between the relevant patient populations, and the absence of an independent comparison on the part of Dr. Hay between the relevant patient populations, the Court has no way to determine whether it was reasonable for Dr. Hay to base his VA damages on data from Medicare Part D, and therefore whether these projections would be relevant or helpful to a jury.

This ruling applies *only* to Dr. Hay's damages calculations for the VA, and does not impact the admissibility of his damages calculations for the Medicare Part D, Medicaid, and Tricare programs.

5. Proximate Cause and Six-Month Window

Teva next argues that Dr. Hay fails to show proximate cause. (Dkt. No. 187 at 4.) This is Teva's third bite at the apple, as the Court rejected Teva's interpretation of Anti-Kickback Statute ("AKS") and False Claims Act ("FCA") causation in two separate opinions. "Relators have met their burden of production for a prima facie case on summary judgment, because they have shown that Teva paid kickbacks to specific physicians (and other health care providers) for the purpose of inducing them to prescribe Azilect and Copaxone, and that the providers then prescribed those drugs. To get to trial, they need not demonstrate that the providers would not have prescribed those drugs absent the kickbacks." *Teva*, 2019 WL 1245656, at *27; (Dkt. No. 181 at 3–6).

Teva next argues that Dr. Hay's alternative damages calculation, which uses a six-month window following Teva's sponsorship of "illegitimate programs" to identify Azilect and Copaxone

prescriptions "resulting from" a violation of the AKS, is not a reliable methodology. (Dkt. No. 187 at 5.)

The Court disagrees. Relators have chosen to prosecute their case under a theory of legal falsity, which means that they are seeking to recoup federal health care program funds that were spent on prescriptions obtained in violation of the AKS, which is putatively material under the FCA. The provision of the AKS upon which Relators rely, in turn, criminalizes, "knowingly or willingly" offering or paying a person "remuneration"—whether a "kickback, bribe, or rebate"—to "induce" that person to "recommend" the purchase of a drug that may be covered by a "Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). Under this theory, a prescription stops "resulting from" a violation of the AKS when the payor no longer intends or expects it to have any effect. *See id.* § 1320a-7b(g). Therefore, it was reasonable for Dr. Hay, as Relators' damages expert, to have used the six-month window during which Teva tracked their speakers' prescriptions following speaker training programs. *See Teva*, 2019 WL 1245656, at *13.

6. "Illegitimate Programs"

Teva next argues that Dr. Hay cannot rely on Dr. Holly Humphrey's identification of "illegitimate programs," because her testimony is inadmissible under *Daubert.* (Dkt. No. 187 at 6.) However, the relevant portion of Dr. Humphrey's testimony is not being excluded. Dr. Humphrey will be allowed to opine on the standards in her profession for both clinical education and continuing medical education ("CME"), and she can opine whether those standards were met by Teva's various programs.

Teva next argues that, even if Dr. Humphrey's testimony is admissible, Dr. Hay was required to independently analyze her criteria for "illegitimate programs," which he admittedly did not do. (*Id.* at 6–7.) This is not correct. Dr. Hay can rely on another expert's opinion about whether a program accords with the medical profession's standards for "educational" programs—

either clinical or CME programs. Here, someone who is an expert in the very field of medical education has opined, based on her experience and familiarity with industry norms, that certain Teva programs would not meet the profession's standards for conferring any sort of educational benefit. That is enough.[3]

Moreover, the cases cited by Teva are all distinguishable, because they involved either attempts to rely on the testimony of experts who would not be called at trial, *see, e.g.*, *TK-7 Corp. v. Estate of Barbouti*, 993 F.2d 722, 730–32 (10th Cir. 1993), or a failure to assess the validity of opinions from colleagues in the same field. In *In re TMI Litig.*, 193 F.3d 613 (3d Cir. 1999), *amended*, 199 F.3d 158 (3d Cir. 2000), for example, the expert admitted that the very principles of risk assessment on which he had relied in generating his report required him to assess the reliability of the other radiation dosage experts' conclusions, which he had not done. *Id.* at 715–16. Here, by contrast, Dr. Hay—an expert in economics who is clearly qualified to come up with a formula for damages—included in that formula information he got from another undoubted experts in her field (*see below*). There is absolutely nothing wrong in his relying on Dr. Humphrey's analysis of which programs did not conform to the educational standards of the medical profession—an area in which she is expert and he is not. *See In re M/V MSC FLAMINIA*, No. 12-cv-8892, 2017 WL 3208598, at *23 (S.D.N.Y. July 28, 2017) ("The portions of Robbins's report that rely upon the findings of other experts to reach his own conclusions employing his independent expertise are, however, admissible."). He then calculated damages using his own expertise.

7. FCA Penalty Provisions

In addition to actual damages, the FCA provides, in part, that

[3] She cannot call them "illegitimate," and neither can Dr. Hay.

> any person who knowingly . . . causes to be presented[] a false or fraudulent claim for payment or approval . . . is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990[.]

31 U.S.C. § 3729(a)(1).

Teva argues that Dr. Hay miscalculates the number of civil penalties, because he levies one penalty for each prescription drug event submitted to any of the four federal health care programs at issue (Medicare, Medicaid, Tricare, and VA). (Dkt. No. 187 at 7.) Citing *United States v. Bornstein*, 423 U.S. 303 (1976), Teva argues that "the focus" should "be upon the specific conduct of the person from whom the Government seeks to collect the statutory forfeitures." *Id.* at 313. Therefore, the appropriate number of forfeitures should correspond to the number of payments Teva made to speakers, not the number of prescriptions those speakers subsequently wrote. (Dkt. No. 187 at 7.)

The Court agrees with Relators that penalizing Teva for each prescription drug event is consistent with the holding of *Bornstein*, in which the United States Supreme Court imposed forfeitures on the subcontractor based on the number of false invoices (three) it had submitted to the prime contractor—who in turn submitted thirty-five invoices to the federal government. *Id.* at 312–13. The Supreme Court reasoned that it was not fair to impose thirty-five civil penalties on the subcontractor, because the number of claims submitted by the prime contractor was "wholly irrelevant, completely fortuitous and beyond [the subcontractor's] knowledge and control." *Id.* at 312. That portion of *Bornstein*'s reasoning has turned out to be an important distinction in "causes to be submitted" FCA cases, with courts holding that a defendant's knowledge of the continuing submission of false claims by an intermediary overrides any fairness concerns about penalizing that defendant for the indirectly-submitted claims. Accordingly, in those cases, courts assess civil penalties based on the number of claims submitted, not any individual "act" of the defendant.

United States v. Inc. Vill. of Island Park, 888 F. Supp. 419, 441 (E.D.N.Y. 1995); *United States ex rel Fahner v. Alaska*, 591 F. Supp. 794, 800 (N.D. Ill. 1984); *United States v. Ehrlich*, 643 F.2d 634, 638 (9th Cir. 1981); *see also United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1157 (2d Cir. 1993) (citing *Ehrlich*, 643 F.2d at 638); *United States v. Medco Health Sys., Inc.*, 223 F. Supp. 3d 222, 230 (D.N.J. 2016), *aff'd sub nom United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89 (3d Cir. 2018).

The same principles apply here, because if the jury finds liability, they will necessarily have found that Teva structured its speaker program intending that, or at least recklessly disregarding the risk that, it would influence or reward prescription writing. Moreover, as discussed in the Court's summary judgment opinion, significant evidence suggests that Teva tracked the prescriptions its speakers wrote. *Teva*, 2019 WL 1245656, at *12–*14.

8. Other Testimony

Finally, Teva has identified certain statements in Dr. Hay's affidavit and rebuttal affidavit that it considers inadmissible. (Dkt. No. 187 at 7–9.)

Dr. Hay's affidavits themselves are hearsay and will not be admitted at trial. Dr. Hay must get on the stand and give direct, sworn testimony. I will take objections to particular questions as they are asked. That said, there are some rules that should be followed in presenting his testimony: Dr. Hay may not speculate about Teva's intent and he may not "characterize" evidence on which he relies (as opposed to summarizing it).

C. Dr. Holly J. Humphrey

1. Dr. Humphrey's Qualifications

Dr. Humphrey, one of Relators' two medical education experts, is a medical doctor who for over fifteen years served as the Dean for Medical Education at the University of Chicago, where she oversaw the entire medical education program, from medical students to residents and

fellows to practitioners.[4] (Expert Report of Holly J. Humphrey, MD, MACP ("Humphrey Report") ¶¶ 1–2, 5, Ex. 1 to Decl. of Timothy J. Geverd ("Second Geverd Decl."), Dkt. No. 189-2; *see also id.* App'x A.) She is also a tenured member of the faculty, who teaches direct patient care and medical professionalism. (*Id.* ¶ 6.) Dr. Humphrey has also served as a member of the American Board of Internal Medicine, as a medical education consultant to several renowned hospitals and universities, and as a site visitor and appeals panelist for accreditation bodies. (*Id.* ¶¶ 4, 8–11.)

Teva does not challenge Dr. Humphrey's extensive qualifications. Rather, Teva argues that her opinions (1) are not the product of a reliable methodology and (2) represent a personal, rather than expert, opinion.

2. Overview of Dr. Humphrey's Report

Dr. Humphrey was asked to "provide information on the structure and standards for medical education in the United States." (*Id.* ¶ 14.) She was also asked to testify whether specific activities sponsored by Teva's speaker programs had any legitimate educational purpose or educational value. (*Id.*)

The Court summarized Dr. Humphrey's testimony when it denied Teva's motion for summary judgment:

> Informed by various third-party standards regarding continuing education for physicians, including publications from the Accreditation Council for Continuing Medical Education, the 2002 and 2008 [Code on Interactions with Health Care Professionals issued by the Pharmaceutical Research and Manufacturers of America (the "PhRMA Guidelines")], the recommendations in the 2009 Huron Consulting report, as well as by her own expertise in medical education, Dr. Humphrey concluded that there would be no educational value for: (a) a physician who attends three or more

[4] Dr Humphrey was Dean for Medical Education when she authored her expert report However, the parties noted in their summary judgment briefs that she no longer holds that position.

> events related to the same drug within six months; (b) a physician who serves as a speaker for a given drug and then attends a lecture about the same drug within twelve months; (c) a physician who attends any speaker program where the food and beverage cost exceeds $65 per person; (d) a physician who serves as a speaker for a given drug where the only audience member is the sales representative or another "ineligible" attendee; (e) a physician who is the only legitimate attendee for an event related to a given drug; and (f) a non-health care professional attendee who is the spouse of a physician for an event related to a given drug. ([Humphrey Report] ¶¶ 38–48.)
>
> Dr. Humphrey based her conclusions on, among other things, the fact that practicing physicians typically build off of their foundational knowledge and clinical experience, and therefore require only one lecture to learn about a new drug or treatment, (*id.* ¶ 50); if a physician still had not learned about the new drug or treatment after the second presentation, a third, identical presentation in a lecture format would have no educational value, (*id.*); the PhRMA Guidelines require that any meals served in connection with a presentation be "modest by local standards," and the average cost of a meal in New York City was less than $65, (*id.* ¶ 52); a lecturer generally has more information, experience, and expertise than one who attends the lecture, such that there would be no legitimate value to "rotating" presenters and audience members, (*id.* ¶ 51), and "one-on-one tutoring sessions are not . . . a legitimate form of medical education," (*id.* ¶ 53).

Teva, 2019 WL 1245656, at *20–*21.

3. Basis for Expert Opinion

Teva first argues that Dr. Humphrey's opinions are inadmissible because they are the result of experience rather than any standard methodology. (Defs.' Mot. *in Limine* to Exclude Expert Op. Test. of Dr. Holly J. Humphrey, Dkt. No. 189 at 3–4.) As I have said, however, "There is nothing wrong with this: the very text of Fed. R. Evid. 702 provides that an expert can be qualified on the basis of his 'knowledge, skill, *experience*, training, or education[.]'" *Veleron Holding, B V. v. Morgan Stanley*, 117 F. Supp. 3d 404, 443 (S.D.N.Y. 2015) (emphasis in original) (quoting Fed. R. Evid. 702); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999) ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and

specialized experience."). Of course, "a proffered expert who relied solely on his or her experience in arriving at his or her expert opinion must have based that opinion on sufficient facts or data, and must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts[.]" *Veleron*, 117 F. Supp. 3d at 444 (internal quotation omitted).

Here, Dr. Humphrey's extensive experience designing, implementing, and conducting professional medical education, as well as her review of the attendance data and supporting documentation at Teva's various speaker programs, qualifies her to opine on whether the following would comport with professional medical education standards[5]:

- A physician who attends three or more events related to the same drug within six months.
- A physician who serves as a speaker for a given drug and then attends a lecture about the same drug within twelve months.
- A physician who serves as a speaker for a given drug where the only audience member is the sales representative or another ineligible attendee.
- A physician who is the only legitimate attendee for an event related to a given drug.
- A non-healthcare professional attendee who is the spouse of a physician for an event related to a given drug.

(Humphrey Report ¶ 48.) This analysis involves applying Dr. Humphrey's subject matter expertise to data in the record, in order to opine on whether speaker programs with these attendees or presenters would be consistent with the requirements for CME programs.

Moreover, Dr. Humphrey's experience also qualifies her to opine on medical education and medical professionals' learning in general, and so she may testify whether the aforementioned

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[5] She cannot call these programs "illegitimate."

practices are consistent with the pedagogical principles and objectives that underlie CME programs.

However, based on her affidavit, I can discern no relevant experience—or "reliable principles," Fed. R. Evid. 702(c)—that would qualify her to opine on whether a speaker program or event where the food and beverage cost exceeds $65.00 per person comports with professional education standards. (Humphrey Report ¶ 48.) This particular portion of her testimony is derived exclusively from language in the PhRMA Guidelines—an industry publication—which states that meals in connection with speaker programs must be "modest by local standards." (*Id.* ¶ 52.) To reach the $65 number, she multiplied Zagat's average cost of dinner in New York City in October 2013 by 133%. (*Id.*) She does not connect the presence of food or beverages at a lecture to any relevant medical education standard or to physicians' learning processes in general; therefore, nothing about Dr. Humphrey's expertise is relevant to either part of this testimony. And, it goes without saying, no expert on medical education is needed to help the jury decide when wining and dining crosses the line into bribery. *Krause v. CSX Transp.*, 984 F. Supp. 2d 62, 81 (N.D.N.Y. 2013) (expert usurps the role of fact finder when they testify "regarding matters that are not scientific or technical or in any way beyond the ken of the average juror"). Therefore, to that limited extent her testimony will not be permitted.

Teva next argues that the aforementioned criteria were reverse-engineered to support the Relators' damages calculations, and that Dr. Humphrey could not possibly have arrived at them independently. (Dkt. No. 189 at 1–2.) Therefore, Teva argues, they are "not an expert opinion at all, but are instead an impermissible recitation of Relators' theory of liability cloaked in Dr. Humphrey's expertise." (*Id.* at 1.)

Teva misstates what Dr. Humphrey actually did in connection with her expert affidavit. Based on the record, which included data about attendance and the average food and beverage cost per person, Relators focused on a subset of suspect criteria, and then asked Dr. Humphrey "to opine on whether [these] specific activities sponsored by Teva's speaker program have legitimate educational purpose and educational value." (Humphrey Report ¶ 14; *see also id.* ¶¶ 43–47.) Dr. Humphrey never represents that she arrived at these criteria independently. (*Id.*) Instead, using her experience, Dr. Humphrey ratified and refined them. For example, based on her expertise in medical education, she conservatively estimated that attending the same program three times in six months would have little value to that attendee, because if information is not absorbed by the second lecture, a third will not make any difference, and it may be necessary to present the information in another format. (*Id.* ¶¶ 49–50.) None of this bears the hallmarks of "reverse engineering."

4. "Educational Value"

Teva moves to exclude Dr. Humphrey's opinion that speaker programs meeting the above criteria lack any "educational value," because she has not reviewed the content of the hundreds of slide decks presented at these events—a task performed by Dr. Samuel Pleasure. (Dkt. No. 189 at 4–5.)

As discussed, an expert "must have based [her] opinion on sufficient facts or data." *Veleron*, 117 F. Supp. 3d at 444 (internal quotation omitted). The Court agrees that Dr. Humphrey cannot condemn entire programs as having "no educational value" based solely on the presence of one of the above program elements, because Dr. Humphrey has not explained how she arrived at that conclusion. However, Relators may argue, and the jury may conclude, that Dr. Humphrey's testimony about whether programs comport with various medical industry standards, together with Dr. Pleasure's testimony about the slide decks, equals programs with no educational value.

5. PhRMA Guidelines

Teva next argues that Dr. Humphrey's expertise does not extend to the PhRMA Guidelines, which are industry guidelines that she had no role in drafting or developing, and therefore that her opinion about them is nothing more than a personal opinion. (Dkt. No. 189 at 4.) Because I have excluded Dr. Humphrey's testimony about whether there is educational value in serving healthcare providers high-end meals or alcohol at a speaker program, this argument is largely moot, as this appears to be the only part of her analysis informed by the PhRMA Guidelines. However, I am not prepared to exclude her testimony about the PhRMA Guidelines entirely at this juncture. To the extent Dr. Humphrey plans to testify about the requirements imposed by the PhRMA Guidelines, Teva's counsel may conduct a brief *voir dire* of Dr. Humphrey for this purpose at trial.

6. Continuing Medical Education ("CME") Standards

Teva argues that Dr. Humphrey cannot testify to the structure and standards for medical education in the United States, since Teva's programs "were not—and were not represented to be—CME programs." (Dkt. No. 189 at 5.) Therefore, her testimony is irrelevant under Fed. R. Evid. 401 and risks confusing the jury under Fed. R. Evid. 403. (*Id.* at 5–6.)

Teva has not met its burden to show that Dr. Humphrey's testimony creates a significant risk of juror confusion. Indeed, Dr. Humphrey's affidavit admits in several places that pharmaceutical speaker programs are not the same as CME. (*See* Humphrey Report ¶¶ 18, 38.) In addition, the Court expects that defense counsel will cross-examine Dr. Humphrey about this important distinction. "Trial courts should be aware of the curative powers of the adversary system when faced with an objection that is solely on the basis of confusion." 4 *Weinstein's Federal Evidence* § 702.02 (2019).

Moreover, Dr. Humphrey's testimony is undoubtedly relevant to the jury's determination of whether Teva designed its speaker programs in a sham manner. *Cf. In re Rezulin Prods*

Liability Litig., 309 F. Supp. 2d 531, 545 (S.D.N.Y. 2004) (excluding medical ethics testimony where expert used the words "reasonable" and "ethical" interchangeably, and only the "due care" legal standard was relevant to adjudicating the case). This is true both because, as observed at summary judgment, certain documents produced by Teva suggest that Teva itself required its speaker bureaus to have an "educational component," *Teva*, 2019 WL 1245656, at *19 n.6, and because the PhRMA Guidelines—which govern—arguably require the same. What the medical profession considers when structuring the education of physicians is therefore relevant to determining whether Teva fulfilled its own requirements that the programs be "educational" and met industry standards for the same.

7. Factual Narrative and Opinion Regarding Intent

Finally, Teva has identified certain statements in Dr. Humphrey's rebuttal affidavit that it considers inadmissible. (Dkt. No. 189 at 6–7.) Again, Dr. Humphrey's affidavits themselves are hearsay and are not admissible. I will entertain objections to particular questions as they are asked. However, Dr. Humphrey will not testify about Teva's intent.

D. Dr. Samuel Pleasure

1. Dr. Pleasure's Qualifications

Dr. Pleasure, the second of Relators' two medical experts, is a neurologist with privileges at the University of California at San Francisco Medical Center ("UCSF") and San Francisco General Hospital, where he has served as an attending physician in the Epilepsy and Multiple Sclerosis Center. (Expert Report and Decl. of Samuel Pleasure, Ph.D., M.D. ("Pleasure Report"), ¶ 3, Ex. 1 to Decl. of Timothy J. Geverd in Supp. of Defs.' Mot. *in Limine* to Exclude Op. Test. of Dr. Samuel Pleasure ("Fourth Geverd Decl."), Dkt. No. 193-1.) Dr. Pleasures also serves as a Professor of Neurology at UCSF, where he holds the Glenn W. Johnson, Jr. Memorial Endowed Chair in Neurology and runs a research laboratory studying neurodevelopmental and

neuroinflammatory disease. (*Id.* ¶ 2.) He frequently acts as the primary educator for medical students on the clinical aspects of neurological diseases—including Multiple Sclerosis and Parkinson's disease. (*Id.* ¶ 3.) In addition, Dr. Pleasure has served on a number of grant panels, the editorial board of several journals, and with the American Neurological Association (ANA); is an active peer reviewer; and is the Neurological Reviews Editor of the Journal of the American Medical Association (JAMA) Neurology. (*Id.* ¶ 4.) He also chaired the ANA's Scientific Program Advisory Committee (SPAC) for two years. In this role, he developed strong familiarity with the nature of organized medical education courses and the requirements for obtaining corporate funding for unbiased educational programs for granting CME credits. (*Id.*)

Teva does not challenge the qualifications of Dr. Pleasure but argues that: (1) his methodology is flawed; (2) his expertise is inapplicable; and (3) his testimony is improper.

2. Overview of Dr. Pleasure's Report

Dr. Pleasure was asked to evaluate the medical educational value of the materials presented at Teva speaker programs. *Teva*, 2019 WL 1245656, at *19.

The Court summarized Dr. Pleasure's report when it denied Teva's motion for summary judgment:

> Dr. Pleasure reviewed the medical information presented across over 500 Teva promotional slide decks for Azilect and Copaxone, including training decks, which were used between 2006 and 2016. (*Id.* ¶¶ 7, 32.) Dr. Pleasure concluded: (a) Teva's materials did not take into account who would be in the audience and what they should receive from an educational perspective, (*id.* ¶¶ 36, 46); (b) the peer-to-peer slide decks were "inappropriate for the education of" practicing neurologists, (*id.* ¶ 37); and (c) the material was not presented in an unbiased way, as required by the PhRMA Guidelines, (*id.* ¶ 39). His principal reasons for so concluding were that the presentations "presented the pathophysiology and clinical features of PD and MS at extremely simplistic levels," which in some cases were "barely appropriate for medical students"; and contained references to studies regarding the use of Teva drugs that were already a few years old and that would already have been

> familiar to treating physicians. (*Id.* ¶¶ 38–40.) Dr. Pleasure also concluded that because Teva required the slides to be presented sequentially and required the materials to be presented in full, the simplistic disease state information at the beginning of the presentation would have caused neurologists "to become inattentive at a very early stage of the presentations." (*Id.* ¶ 38.)
>
> Dr. Pleasure also opined that, while there were "interesting and important advances in the field of clinical care of MS and PD" between 2004 and 2016, Teva's slide decks did not present this information in a full and unbiased way, such as to have educational or practical value for neurologists attending these presentations. (Rebuttal Expert Report and Declaration of Samuel Pleasure, Ph.D., M.D. ("Pleasure Rebuttal Report"), DX90 ¶ 11.) For example, the presentations did not disclose that the placebo group in the PRECISE trial "contained patients at a higher risk to develop MS than the treatment group," and the GALA trial was a placebo-controlled trial, rather than a head-to-head comparison of Copaxone against other agents. (*Id.*) Dr. Pleasure also opined that neurologists would already have been familiar with these studies through medical journals and other literature. (*Id.*)

Id.

3. "Reverse-Engineering"

Teva first argues that Dr. Pleasure's opinions were reverse-engineered and therefore, inadmissible. (Defs.' Mot. *in Limine* to Exclude Expert Op. Test. of Dr. Samuel Pleasure, Dkt. No. 193, at 2.) In particular, Teva harps on Dr. Pleasure's conclusion that Teva's programs failed to provide answers to three questions he identified as "principal in designing any program with an educational component": (1) Who should be in the audience? (2) What is the background and experience of the intended audience? and (3) What knowledge or education will be valuable for the intended audience members? (Pleasure Report ¶ 35.) Teva claims that these criteria are created out of "whole cloth" and that Dr. Pleasure "crafted a test" to reach the conclusion that Teva's materials lacked educational value. (Dkt. No. 193 at 2.)

But Teva points to nothing suggesting that Dr. Pleasure reached a conclusion prior to reviewing the underlying facts. *Cf. Faulkner v. Arista Records LLC*, 46 F. Supp. 3d 365, 381

(S.D.N.Y. 2014); *see also In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396, 430 (S.D.N.Y. 2016) (expert testimony inadmissible when expert was "given a conclusion by lawyers and worked backwards to hypothesize a mechanism by which it might occur"). What Dr. Pleasure said is that these three questions encapsulated what he had identified as deficient about Teva's programs, based on his experience in designing educational programs. There is no evidence that his review was cursory, "aimed at achieving one result," or violated any standard scientific methodology, which would be impermissible. *Faulkner*, 46 F. Supp. 3d at 481.

4. Basis for Expert Opinion

Teva next argues that Dr. Pleasure's opinions are not the product of any methodology, because they are based on an "anecdotal account" of his own experiences, specifically his experience designing and attending educational programs. (Dkt. No. 193 at 3.) As I have already discussed in the context of Dr. Humphrey, *see supra*, Fed. R. Evid. 702 permits an expert to be qualified on the basis of experience. *See also Veleron*, 117 F. Supp. 3d at 443. Dr. Pleasure's substantial experience in the field of neurology and his experience in creating educational programming for fellow physicians, qualify him as an expert in this field. To the extent Teva argues that Dr. Pleasure is not qualified to interpret industry guidelines, the Court agrees Teva may—as with Dr. Humphrey—briefly *voir dire* him at trial. This is not—as Teva attempts to present it—a situation in which a technical or scientific expert has failed to address pertinent evidence or data and relied only on experience. Rather, it is one in which experience itself is the "sufficient facts and data" necessary for the expert opinion. *Id.* at 447.

5. Factual Support

Teva next argues that Dr. Pleasure's opinions lack factual support because he relied only on Teva's slide deck materials to determine the educational value of the program, despite recognizing that the slide decks do not reflect the entirety of the program. (Dkt. No. 193 at 3–4.)

In particular, Teva takes issue with Dr. Pleasure's dependence on discussions with Relators and counsel to provide him with information regarding the speaker program, claiming that he erred by not considering relevant deposition testimony. (*Id.*)

Teva misrepresents Dr. Pleasure's testimony. Dr. Pleasure testified that he read and considered the deposition testimony, and that the conversations he had with the Relators were for further clarification. (Ex. 8 to Fourth Geverd Decl., Dkt. No. 193-9 at 187:1–18.) This statement is supported by his discussion of depositions in his report. (Pleasure Report ¶¶ 49–54.) The fact that Dr. Pleasure conducted no additional investigation into Teva's promotional speaker program on his own, but instead relied on deposition testimony as well as conversations with the Relators and with Relators' counsel, does not preclude admitting his testimony. Such arguments—which are limited, as Teva has pointed to little evidence that Dr. Pleasure's misplaced reliance significantly impacted his conclusions—are appropriate for cross-examination. *Namenda*, 331 F. Supp. 3d at 174 (arguments that expert's testimony is "speculative, internally inconsistent, and contradicted by the evidence" best addressed by cross-examination); *see also Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 266–67 (2d Cir. 2002).

Teva also makes a brief (one sentence) argument that Dr. Pleasure may not introduce hearsay evidence Relators provided to him and that "oftentimes is at odds with the facts elicited through discovery[.]" (Dkt. No. 193 at 5.) Experts are permitted to rely on hearsay to conduct their analysis but are not permitted to be called simply for the purpose of introducing hearsay. *See United States v. Dukagjini,* 326 F.3d 45, 59 (2d Cir. 2003) (excluding evidence when "the expert was repeating hearsay evidence without applying any expertise whatsoever, thereby enabling the government to circumvent the rules prohibiting hearsay"). Teva has pointed to no particular portion of Dr. Pleasure's testimony in which he serves as a "conduit" for hearsay and should

therefore be inadmissible. A general allegation does not suffice to meet Teva's burden. If Dr. Pleasure is asked an objectionable question, I will rule at the time it is asked.

6. Personal Opinions

Teva's next argument is that Dr. Pleasure's opinions regarding industry guidance are "inadmissible personal opinions" because—despite having a limited understanding of the PhRMA and FDA Guidelines—he believes that compliance with these industry guidelines and federal regulations as they apply to promotional speaker programs is insufficient to establish a program that is valuable to physicians. (Pleasure Br. at 5.)

An expert may not opine on his own personal view of the efficacy of the standards that a pharmaceutical company should "ideally" adhere to if it will not assist the fact-finder determine an issue in the litigation. *Rezulin,* 309 F. Supp. 2d at 560; see *also Mirena*, 169 F. Supp. 3d at 486. Here, Dr. Pleasure's opinions about the veracity and value of the standards are his personal opinion, not an "expert opinion" and are ultimately, of no use to the fact-finder. *See In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liability Litig.*, No. MDL 1203, 2001 WL 454586, at *18 (E.D. Pa. Feb. 1, 2001). Accordingly, Dr. Pleasure's testimony on the on the value of promotional versus nonpromotional programs as set forth in his expert report will not be admitted.

7. "Educational Value"

Teva moves to exclude Dr. Pleasure's assessment of Teva's speaker program materials because his experience is in medical education, rather than promotional programs. Teva argues that his opinion comparing Teva's speaker programs to the educational value in medical education programs is irrelevant. (Dkt. No. 193 at 6–7.)

But this Court has already found that Dr. Pleasure's opinions were relevant to a "material fact" in this case—whether Teva created its content for its presentations in a sham manner. *Teva*,

2019 WL 1245656, at *19. Teva's programs are required to have an educational element, and Dr. Pleasure's experience in medical education (as well as his experience as a neurologist with expertise in MS and Parkinson's disease) provides him with the expertise to opine on the educational value of the given presentations.

Moreover, Teva's argument that the jury would be misled as to the standards to which Teva's programs were subject has no merit. Dr. Pleasure's testimony does not impose educational standards on Teva's promotional programs, and I see no reason why his opinions would mislead the jury.

8. Narration and Teva's Intent

Teva next argues that Dr. Pleasure's narration and characterization of deposition testimony, specifically in paragraphs 49–54 of his report, is improper and inadmissible. (Dkt. No. 193 at 7.)

An expert may not "rehash[] otherwise admissible evidence about which he has no personal knowledge," including when it is presented as "background" to his expert testimony. *Highland Capital Mgmt , L.P. v. Schneider*, 379 F. Supp. 2d 461, 468–69 (S.D.N.Y. 2005); *see also Rezulin*, 309 F. Supp. 2d at 541 & n.20. Dr. Pleasure's report includes descriptions of deposition transcripts of physician speakers in the promotional program and Teva employees responsible for organizing and promoting the sessions. Dr. Pleasure will not be permitted to summarize what he has read. However, this does not preclude him from testifying to the fact that he read the testimony of particular people on particular subjects (which testimony will already have been presented to the jury)—drawing the jury's attention to "particularly relevant passages," *Island Intellectual Prop. LLC v Deutsche Bank AG*, No. 09-cv-2675, 2012 WL 526722, at *2 (S.D.N.Y. Feb. 14, 2012)—prior to testifying about his conclusions.

Finally, as discussed in the context of Teva's efforts to exclude the testimony of Dr. Humphrey, Dr. Pleasure will not be permitted to opine on Teva's intent in conducting its speaker program, which is a question solely for the jury.

E. Paul W. Kim

Relators supposedly proffer Mr. Paul W. Kim as an expert to provide opinion testimony regarding the effectiveness of Teva's compliance program with respect to its speaker program. However, Mr. Kim's name does not appear on Relator's (or Teva's) witness list. (Dkt. No. 203 at 50–51.)

Defendants move to excluded Mr. Kim's testimony on various grounds. (*See* Dkt. No. 191.) The only ground that matters is that he is not on the witness list. He will not be permitted to testify. The motion is GRANTED.

II. Defendants' Other Motions *in Limine*

A. Motion *in Limine* to Preclude Evidence or Argument About Any Teva Employee's Disciplinary History or Alleged Violation of Teva's Policies That Is Unrelated to the Promotional Speaker Program

Teva moves *in limine* to preclude evidence or argument about any Teva employee's disciplinary history or alleged violation of Teva's policies that is unrelated to the Promotional Speaker Program. (Dkt. Nos. 194, 195.) The motion is not opposed. (Dkt. No. 244 at 2.) It is granted.

B. Motion *in Limine* to Preclude Tim Turner from Testifying Regarding Certain Matters of Which He Lacks Personal Knowledge and Providing Inadmissible Lay Opinion Testimony

Teva moves *in limine* to preclude Tim Turner from testifying about matters as to which he allegedly lacks knowledge, or from providing lay opinion testimony. (Dkt. Nos. 196, 197.) Turner is a former Teva employee. He testified at his deposition that he did not "have a good

understanding of how Teva Neuroscience chose its speaker" and that he had not "personal" or "direct knowledge" about Relators' allegation that Teva selected speakers based on their history of prescribing Azilect and Copaxone. (Dkt. No. 197 at 2.) Relators insist that Turner does have some personal knowledge about how speakers were selected—pointing to at least one instance in which Turner was involved in training a speaker. (Dkt. No. 239 at 1–3.)

The motion is silly. Turner is not on either party's witness list and so will not be allowed to testify to *anything* at trial. I will not permit him to be added as a witness at this late date.

C. Motion *in Limine* to Preclude Relators Charles Arnstein and Hossam Senousy From Testifying Regarding Certain Matters of Which They Lack Personal Knowledge

Teva moves *in limine* to preclude Relators from testifying about matters of which they lack personal knowledge. (Dkt. Nos. 198, 199.) The motion *in limine* is denied because it is impossible to assess what Relators will be asked at trial. We will rule on a question by question basis during the trial. I very much doubt that Relators will be barred from giving any and all testimony on the subject of speaker selection on the ground asserted by Teva.

D. Motion *in Limine* To Preclude Relators from Introducing Recording of Gary Smith Into Evidence at Trial

Teva moves *in limine* to preclude Relators from introducing a recording of Gary Smith into evidence at trial. (Dkt. Nos. 200, 201.) Relator Arnstein surreptitiously recorded a presentation by Smith at the Central Area Sales Meeting in Chicago. (*See* Dkt. No. 201 at 1.) Defendant asserts that recording Smith without his consent violated Illinois law—specifically, the Illinois Eavesdropping Act, 702 Ill. Comp. Stat. §§ 5/14-2, 5/14-4(a). (*Id.* at 1–4.) Relators counter that Teva has misapplied Illinois law and notes that nothing about the recording violates federal law. (Dkt. No. 238 at 1.)

The motion is denied. This case involves violations of federal, not state, law. As a result, as long as one party to the recording (Smith) consented to the making of the recording, it is admissible unless the recording was made as part of a criminal or tortious act. *Century Consultants Ltd. v. The Miller Grp., Inc.*, 2005 WL 3108455, at *1 (C.D. Ill. 2005). It was not.

E. Motion *in Limine* To Preclude Evidence of Violations of Industry Standards, Agency Regulations, and Internal Policies

Teva moves *in limine* to preclude evidence of violations of industry standards, agency regulations, and internal policies. (Dkt. Nos. 202, 204.)

Defendants may as well have called their motion "Motion to Preclude Relators from Putting in a Case." The motion is denied. The proposed evidence may be prejudicial to Teva, but it is not unfairly so.

F. Motion *in Limine* To Exclude Advanced Health Media Speaker Program Attendee Data

Teva moves *in limine* to exclude Advance Health Media Speaker Program Attendee Data. (Dkt. Nos. 205, 208.) The motion is denied for substantially the reasons outlined in Relators' opposition brief. (*See* Dkt. No. 247.) If Teva thinks that the AHM records—which were prepared from Teva's own business records—are in any way flawed, they should bring that out on cross examination.

G. Motion *in Limine* To Preclude Relators from Referencing or Making Argument Regarding Green Envelopes

Teva moves *in limine* to preclude Relators from discussing "green envelopes." (Dkt. Nos. 213, 220.) Specifically, they wish to preclude argument that, by placing payments for speakers into green envelopes, Teva was conveying a "tacit message" that speakers would make more money if they wrote more prescriptions. (Dkt. No. 220 at 1.) Teva insists that "everything from

Teva is green," and that no evidence was found during discovery that would support such an argument. (*Id.* at 2–3.)

I find Relators' arguments in opposition to this motion not just weak, but specious. (*See* Dkt. No. 234.) It is granted.

H. Motion *in Limine* To Preclude Relators from Referencing or Introducing Evidence Relating to Teva's Advisory Boards and Preceptorships at Trial

Teva moves *in limine* to preclude Relators from refereeing or introducing evidence about Teva's Advisory Boards and Preceptorships (Dkt. Nos. 221, 222), on the ground that Relators never asserted a claim that the use of Advisory Boards and Preceptorships violated the False Claims Act until they filed the Pre-Trial Order (Dkt. No. 222 at 2–3). In particular, Teva points to Relators' response to a contention interrogatory propounded in this case, in which there is no reference to either Advisory Boards or Preceptorships—only to paid speakers programs. (*Id.*)

Relators argue that evidence about the fact that particular physicians were on Teva Advisory Boards or held Preceptorships relates to the issue of witness bias. (Dkt. No. 236 at 3–4.) I agree that any form of compensation physicians receive from Teva can be used to show bias, so the motion is denied. However, the jury will be instructed that there is no allegation that either Advisory Board membership or Preceptorship violates the False Claims Act and that they can only consider evidence of participation in such Teva programs for the limited purpose of witness bias in favor of defendant.

I. Motion *in Limine* to Preclude Evidence or Argument Regarding Irrelevant Conduct Underlying Settlement Agreements, Claims, Investigations, and Litigation

Teva moves *in limine* to preclude evidence or argument regarding what is calls "irrelevant conduct underlying settlement agreements, claims, investigations and litigation." (Dkt. Nos. 223, 224.) Relators "do not oppose the relief sought in this motion *in limine*." (Dkt. No. 233 at 2.) The

motion is granted. If it should be necessary to reference the Corporate Integrity Agreement that was entered into by Teva's predecessor, Cephalon, I should be notified first thing on that morning, so we can craft appropriate information to be conveyed to the jury.

J. Motion *in Limine* to Exclude Evidence of FDA Letters

Teva moves *in limine* to exclude evidence of two letters from FDA employees. (Dkt. Nos. 225, 226.) The letters contend that certain Teva paid speaker presentations did not comply with FDA regulations. (Dkt. No. 226 at 1.) It contends that the letters are not probative of the claims in suit, are hearsay, are not admissible as either public records or business records of the FDA, and are being introduced to show propensity in violation of Fed. R. Evid. 404(b).

The motion is denied. The letters do not violate Rule 404(b); they are not offered for propensity, but to demonstrate that, aside from information that the FDA told Teva it could not offer in its programs (about off-label uses of Copaxone), Teva had nothing new to convey to those who attended the programs. (*See* Dkt. No. 241 at 3.) They are not hearsay; FDA warning letters are admissible pursuant to Fed. R. Evid. 803(8). (*Id.* at 3–5.)

PLAINTIFF-RELATORS' MOTIONS IN LIMINE

A. Motion *in Limine* to Exclude Evidence and Argument Concerning the Fair Market Value for Speaker Services

Relators move *in limine* to exclude evidence and argument concerning the fair market value for speaker services. (Dkt. Nos. 206, 207.) The motion is denied. We will deal with safe harbor arguments in motions addressed to the court after I hear all the evidence. It is too early for directed verdict motions.

B. Motion *in Limine* to Exclude Evidence and Argument Regarding the Quality of Teva's Drugs, Patient Harm, and Teva's Corporate Character

Relators move *in limine* to exclude evidence and argument about the quality of Teva's drugs, patient harm, and Teva's corporate character. (Dkt. Nos. 209, 210.) This overbroad motion is denied for substantially the reasons set out in Teva's opposing brief. (*See* Dkt. No. 232.)

C. Motion *in Limine* to Exclude Declarations and Testimony from Undisclosed Expert Witnesses

Relators move *in limine* to exclude testimony from "undisclosed expert witnesses." (Dkt. Nos. 211, 212.) Since no new experts may be designated and no one who has not already put in a report in compliance with Fed. R. Civ. P. 26 will be allowed to testify, I cannot understand why this motion was made in the manner that it was. Apparently, Relators think that three physicians whom Teva plans to call at trial as fact witnesses are secretly being proffered as experts. (*See* Dkt. No. 212 at 1.) They are wrong. And, of course, the doctors will necessarily draw on their specialized expertise as physicians when they testify—just as treating physicians necessarily draw on their expertise when they testify about the treatments that they give their patients. The motion is denied. Moreover, the doctors will be permitted to offer lay opinion testimony about Teva's promotional speaker program materials and its content development process.

D. Motion *in Limine* to Exclude Evidence Regarding Defendants' Compliance Policies and Enforcement Actions for Areas Unrelated to Speaker Programs for Copaxone and Azilect

Relators move *in limine* to exclude evidence about Defendants' compliance policies and enforcement actions that are not related to the Copaxone and Azilect speaker programs. (Dkt. No. 214, 215.) The motion is granted. Frankly, we have enough to do without delving into areas that have nothing to do with these programs. I do not understand that the law permits Teva to defend against Relators' charges by asserting that complying with the rules relating to paid speakers is a

lower priority item on Teva's "to do" list, so Dr. Smollen's opinions about "overall compliance" and "priorities" appear to me to be irrelevant. (*See* Dkt. No. 215 at 1–3.)

E. Motion *in Limine* to Exclude Reference to Civil Penalties and Statutory Treble Damages

Relators move *in limine* to preclude any reference to civil penalties or statutory treble damages at trial. (Dkt. Nos. 216, 217.) Teva concedes that such references are inappropriate (Dkt. No. 230 at 1), so the motion is granted.

Teva tries to sneak in an extra *in limine* motion by asserting that the jury should measure damages by looking to the number of acts committed by Teva, rather than the number of claims submitted to the Government. (*Id.* at 1–2.) The Court declines to address Teva's argument because it was not properly presented, and, in any event, the Court already dismissed this argument when Teva raised it in connection with its *Daubert* motion to exclude the expert testimony of Dr. Hay.

F. Motion *in Limine* to Exclude Evidence or Any Argument as to Whether Teva Specifically Intended a Government Healthcare Program to Pay for Prescriptions Resulting From Bribes

Finally, Relators move *in limine* to exclude evidence or argument about whether Teva "intended a Government healthcare program to pay for prescriptions resulting from bribes." (Dkt. Nos. 218, 219.) This motion apparently arises out of a jury instruction on intent that is proposed by Teva. (Dkt. No. 219 at 2.) *In limine* motions are not an appropriate vehicle for addressing jury instructions. They are addressed to evidence, not to issues of law.

However, in case anyone is interested, the jury will be instructed that Relators must prove that Teva acted "willfully"—which is to say, with knowledge that its conduct was unlawful and the specific intent to do something that the law forbids. In this case, the law forbids "offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to refer an individual to a

person for the furnishing or arranging for the furnishing of any item or service for which payment *may be made* in whole or in part under a Federal health care program[.]" 42 U.S.C. § 1320a-7b(b)(2)(A) (emphasis added); *see also United States v. Miles*, 360 F.3d 472, 480 (5th Cir. 2004) (AKS extends to "an item or service that *could be paid for* by a federal health care program") (emphasis added). Relators need not prove that Teva specifically intended that the referrals generated be reimbursed specifically by Medicare, Medicaid, or any other federal health care program (versus any private health insurer). Rather, under both the AKS and the FCA, it need only be foreseeable.

CONCLUSION

This constitutes the decision and order of the Court.

The Clerk of Court is respectfully requested to close the motions at Docket Numbers 186, 188, 190, 192, 194, 196, 198, 200, 202, 205, 206, 209, 211, 213, 214, 216, 218, 221, 223, and 225.

Dated: July 1, 2019

Chief Judge

BY ECF TO ALL PARTIES